



June 26, 2018

Via Federal Express

Ms. Kathryn J. Olson
Chair
Illinois Health Facilities and Services Review
Board
525 West Jefferson Street, 2nd Floor
Springfield, Illinois 62761

Re: Opposition to Dialysis Care Center Rockford (Proj. No. 17-070)

Dear Ms. Olson:

DaVita Inc. submits this sworn statement in opposition to the Dialysis Care Center Rockford CON permit application for in-center hemodialysis services in Rockford, Illinois ("DCC Rockford"). At the recent April 17, 2018 meeting, the Illinois Health Facilities and Services Review Board ("HFSRB") denied DaVita's application for a smaller 8 station facility to be located in south Rockford due to lack of station need and underutilized facilities. ***Since the denial of DaVita's application, nothing has changed.*** Additionally and discussed more fully in this letter, the Alpine Dialysis facility was far better positioned to address the need for dialysis in Rockford. Further, the DCC Rockford application has many flaws and deficiencies that were not present in the Alpine Dialysis application:

- Insufficient documentation related to projected utilization,
- Negative impact on area dialysis clinics,
- Inadequate staffing plan,
- No written affiliation agreement,
- False assurance that DCC Rockford will achieve 80% utilization by the second year of operation,

- Lack of sufficient cash and securities to fund the project, and
- Project cost and funding misinformation.

Also, Dialysis Care Center has no proven track record of providing care that is superior in quality to other established providers and, further, its owners have consistently repeated a false narrative that proposed facilities are necessary to provide respite dialysis. However, respite dialysis is a very minor segment of in-center dialysis facility utilization and does not in any way warrant additional capacity. For these reasons, DaVita respectfully requests the HFSRB deny Dialysis Care Center's application for a larger 12 station dialysis facility in Rockford.

1. Alpine Dialysis Merits Compared to DCC Rockford Deficiencies

At the April 17, 2018 meeting, the HFSRB denied DaVita's application for an 8 station dialysis facility to be located in south Rockford to be known as Alpine Dialysis. DaVita's Alpine Dialysis application was a better application on its face and was better positioned to serve the underserved patients in south Rockford where there is no dialysis facility. The map attached as Exhibit 1 shows the locations of all of the existing Rockford area in-center dialysis facilities as well as the proposed location for each of the Alpine Dialysis facility and the DCC Rockford facility.¹ The proposed DCC Rockford facility will be located farther north in an area that is already well-served by in-center facilities and less than five miles from three existing facilities. Importantly, Churchview Dialysis is less than a mile from the proposed DCC Rockford facility and was operating at 59% utilization as of March 31, 2018. This means there is time on the schedule for an additional 59 patients at this facility alone. Further, based upon its own pre-ESRD data, only 8.33% of its projected dialysis patients reside in the zip code where the proposed DCC Rockford dialysis clinic will be located, and other patients targeted to be served by this proposal are dispersed throughout the County.² In contrast, the Alpine clinic was targeted to serve the immediate community around the site selected: 61109 (59 patients) and 61104 (10 patients). The north Rockford area is already well-served by existing clinics, and additional stations are not warranted, particularly given the lack of referral data provided in the application as discussed below.

2. Flaws and Deficiencies of DCC Rockford Proposal

As documented in the HFSRB staff report, the Alpine Dialysis project had only two negative findings: (1) calculated excess of stations in the planning area and (2) unnecessary duplication of services. ***The DCC Rockford proposal is inferior to the Alpine Dialysis application in many ways and should receive an unprecedented 10 negative findings.*** DaVita is always respectful of HFSRB requirements in planning a new site. It works hard to satisfy the

¹ Red dots represents the locations existing operational facilities, the green dot represents the proposed location of Alpine Dialysis, and the blue dot represents the proposed location of DCC Rockford facility.

² See Dialysis Care Center Rockford Application for Permit pp 190-198.

HFSRB requirements and invests significant time and money to put forth its proposals for expansion of services. We expect other applicants to behave similarly. It would be inappropriately biased for another applicant to receive favorable treatment for such a deficient application.

a. Negative Findings

The Alpine Dialysis project had only two negative findings: (1) Planning Area Need and (2) Unnecessary Duplication of Service, Maldistribution of Service, Impact on Other Providers.³ Since the April 17, 2018 HFSRB meeting, nothing has changed. Further, like Alpine Dialysis, there are underutilized dialysis clinics within the 30 minute geographic service area of DCC Rockford. Accordingly, DCC Rockford must receive negative findings on these criteria.

i. Planning Area Need (Criterion 1110.230(b))

This criterion requires applicants to “document that the number of stations to be established or added is necessary to serve the planning area's population.”⁴ To satisfy this criterion, “[t]he number of stations proposed *shall not exceed the number of the projected deficit*, to meet the health care needs of the population served, in compliance with the utilization standard specified in 77 Ill. Adm. Code 1100.”⁵ As of the June 11, 2018 monthly update of end-stage renal disease (“ESRD”) stations, there is an excess of 4 stations in HSA 1.⁶ Accordingly, a negative finding must be made for this criterion.

ii. Unnecessary Duplication of Service, Maldistribution of Service, Impact on Other Providers (Criterion 1110.230(c))

To satisfy this criterion, an applicant must document, among other things, historical utilization (for the latest 12-month period prior to submission of the application) for existing clinics is above the HFSRB's 80% utilization standard. There are seven dialysis clinics within 30 minutes of DCC Rockford. As of March 31, 2018, average utilization of these clinics was 65%. Excluding the three clinics currently in ramp up, utilization of the four remaining clinics was 76%. There is sufficient capacity at the existing clinics to accommodate the projected DCC Rockford dialysis patients. Accordingly, a negative finding must be made for this criterion.

³ Illinois Health Facilities and Services Review Board, Alpine Dialysis, DaVita Alpine Dialysis Supplemental State Board Report 3 (Apr. 17, 2018) *available at* <https://www2.illinois.gov/sites/hfsrb/Projects/ProjectDocuments/2017/17-039/18.%2017-039%20DaVita%20Alpine%20Dialysis%20Supplemental%203.pdf> (last visited Jun. 22, 2018).

⁴ 70 Ill. Admin. Code 1110.230(b).

⁵ *Id.* (emphasis added).

⁶ Illinois Health Facilities and Services Review Board, Update of Inventory of Other Health Services (includes ASTC, ESRD and Alternative Models) (Jun. 11, 2018) *available at* <https://www2.illinois.gov/sites/hfsrb/InventoriesData/MonthlyHCFInventory/Documents/OTHER%20SERVICES%20INVENTORY%20UPDATE%20June%2011%202018.pdf> (last visited Jun. 22, 2018).

b. Deficiency #1: Insufficient Documentation Relating to Projected Utilization (Criterion 1110.120(b))

The DCC Rockford referral letter does not justify another dialysis facility; it doesn't even come close to it. As specified in the HFSRB's rules, the CON permit application must include a nephrologist attestation to document that a sufficient number of ESRD patients to justify the establishment of an additional facility will be referred to the proposed dialysis facility. This HFSRB rule provides that "[t]he anticipated number of referrals cannot exceed the physician's documented historical [ESRD patient] caseload."⁷ In the referral letter Dr. Mahmood provided, it states that 70 patients will be referred to the planned facility,⁸ yet he documents only referring four patients for dialysis in 2017.⁹ Therefore, this referral letter hardly justifies a single station let alone a new facility location.

Based on the data provided in the physician referral letter, the CON permit application fails to meet this criterion.

c. Deficiency #2: Establishment of In-Center Hemodialysis Services (Criterion 1110.230(b)(3))

This criterion requires applicants to demonstrate the proposed number of stations is necessary to accommodate service demand. For projects for the establishment of new facilities, the applicant must document:

- (1) the physician's total number of patients (by facility and zip code of residence) who have received care at existing facilities located in the area for the most recent 3 years and the end of the most recent quarter,
- (2) the number of new patients (by facility and zip code of residence) located in the area the physician referred for in-center hemodialysis for the most recent year, and
- (3) an estimated number of patients (transfers from existing facilities and pre-ESRD, as well as respective zip codes of residence) that the physician will refer annually to the applicant's facility within a 24-month period after project completion.

With respect to this criterion, the letter falls short of the requirement in several respects. First, three years along with the most recent quarter of historical data were not provided. The Applicants only provided 2015 and 2016 historical data; 2014 and Q3 2017 should also have been provided.¹⁰ Further, the physician group's peak census occurred in 2016 with 5 patients. Again, this figure hardly justifies a single station. Second, and as discussed more fully in

⁷ 70 Ill. Admin. Code 1110.230(b)(3)(B)(iii).

⁸ See Dialysis Care Center Rockford Application for Permit p 188

⁹ Id. at 202-203.

¹⁰ Id. at 199-201

Section 2.a, Dialysis Care Centers failed to document a sufficient number of new admissions within the latest 12 month period to justify 70 new admissions to a new facility within the first two years after project completion. Dialysis Care Centers fails to satisfy this criterion.

d. Deficiency #3: Negative Impact on Other Area Providers (Criterion 1110.230(c)(3))

Pursuant to the HFSRB's rules, applicants must document a proposed facility will not lower the utilization of existing facilities below the HFSRB's standards or lower to a further extent utilization of existing providers currently operating below the HFSRB's standards.¹¹ Because DCC Rockford's referral letter does not establish a discrete patient base to be served, it will clearly adversely affect existing dialysis clinics in Rockford. In addressing Impact of Project on Other Area Providers criterion in its application, Dialysis Care Centers states, "[t]he proposed dialysis facility will not have an adverse impact on existing facilities in the proposed geographic service area. All of the identified patients will be referrals from identified physicians and are on the pre-ESRD list. No patients will be transferred from other existing dialysis facilities."¹²

This statement contradicts other statements in the application that indicate patients will transfer from existing facilities. *"The choice to change providers is one seen frequently within healthcare, dialysis treatment included."*¹³ Coupled with the fact Dialysis Care Centers provided insufficient historical patient data to justify the proposed 12 stations facility, it is clear that the real plan Dialysis Care Centers' physician partners have is to transfer current ESRD patients from existing facilities and thereby lower utilization of existing facilities below or further below the HFSRB's standard. Dialysis Care Centers fails to satisfy this criterion.

e. Deficiency #4: Inadequate Staffing Plan (Criterion 1110.230(e))

All applicants are required to provide a staffing plan for a proposed dialysis facility.¹⁴ In its application, Dialysis Care Centers provides no plan and does not otherwise explain how the positions will be filled as required by Sec. 1110.230(e)(2)(B) of the HFSRB's rules. Dialysis Care Centers state:

Upon opening, the facility will hire a Clinic Manager who is a Registered Nurse (RN). This nurse will have at least twelve months experience in a hemodialysis center. Additionally, we will hire one Patient Care Technician (PCT). After we have more than one patient, we will hire another RN and another PCT.¹⁵

¹¹ 70 Ill. Admin. Code 1110.230(c)(3).

¹² See Dialysis Care Center Rockford Application for Permit p 113.

¹³ Id. at 87, 103

¹⁴ 70 Ill. Admin. Code 1110.230(e).

¹⁵ See Dialysis Care Center Rockford Application for Permit p 114.

The Medicare Conditions of Participation require registered nurses to have “at least 12 months of experience in facility nursing, and [at least] an additional 3 months of experience in providing nursing care to patients on maintenance dialysis.”¹⁶ Dialysis Care Centers has no in-center dialysis presence within Rockford or anywhere in Winnebago County. The only meaningful option to comply with the Medicare Conditions of Participation would be to recruit registered nurses from existing clinics in the area. In fact, Dialysis Care Centers have already contacted DaVita teammates in the Rockford area about working at the proposed DCC Rockford facility.

DaVita heavily invests in teammate training. New teammates participate in DaVita Academy, a two day off-site foundational training and development program. Additional training for facility teammates includes introduction to the dialysis machine, components of the hemodialysis system, infection control, anticoagulation, patient assessment/data collection, vascular access, and kidney failure. DaVita’s extensive training program has been repeatedly recognized by *Training* magazine for its whole person approach to training and development. For each teammate recruited by DCC Rockford, DaVita must recruit and train additional staff to ensure its facilities maintain compliance with Medicare staffing requirements, which is both expensive and time consuming.

Given Dialysis Care Center offers no plan for recruiting facility staff, Dialysis Care Centers fails to satisfy this criterion.

f. Deficiency #5: Failure to Provide for Continuity of Care (Criterion 1110.230(h))

The HFSRB regulations state, “[a]n applicant proposing to establish an in-center hemodialysis category of service shall document that a signed, written affiliation agreement or arrangement is in effect for the provision of inpatient care and other hospital services.” Dialysis Care Centers states it has a written affiliation agreement with a hospital for the provision of inpatient care and other services; however, no such affiliation agreement was provided as is required by the HFSRB rules.¹⁷ The DCC Rockford application fails to meet the Continuity of Care criterion. In fact, we are surprised the application was deemed complete without this information.

g. Deficiency #6: False Assurances (Criterion 1110.230(j))

This criterion requires an applicant to submit a signed and dated statement attesting that by the second year of operation after project completion, the applicant will achieve and maintain the HFSRB’s utilization standard of 80%. While Dialysis Care Centers completed this attestation, as noted above, Dialysis Care Centers’ historical referral data does not justify the

¹⁶ 42 C.F.R. §494.140(b) (emphasis added).

¹⁷ *Id.* at 122.

number of patients anticipated to initiate dialysis within the first two years after project completion. Accordingly, the attestation is flawed and HFSRB staff should make a negative finding on the Assurances criterion based on this shortcoming.

h. Deficiency #7: Lack of Availability of Funds (Criterion 1120.120))

Applicants must document that sufficient financial resources will be available to pay for the estimated total project cost plus any related project costs by providing evidence of sufficient financial resources. Dialysis Care Centers state: (i) DCC Rockford will be funded through cash and cash equivalents and a lease and (ii) the DCC Rockford application meets the criteria for the financial viability waiver.¹⁸ To qualify for the financial viability waiver, an applicant must document "internal resources availability shall be available as of the date the application is deemed complete."¹⁹ Dialysis Care Centers provided no financial information that documents sufficient financial resources to fund the proposed DCC Rockford capital expenditures. The Chief Operating Officer's certification that Dialysis Care Centers maintain sufficient cash and short term securities to fund the project²⁰ does not satisfy the financial viability waiver requirements.

Dialysis Care Centers do not qualify for the financial viability waiver and must receive a negative finding for this criterion.

i. Deficiency #8: Project Cost and Funding Misinformation

Pursuant to the HFSRB regulations, an applicant must provide the estimated total project cost, including the amounts for each cost component (line item) applicable to the project. In the project costs and sources of funds worksheet, Dialysis Care Centers included no construction or modernization costs and only \$60,000 in contingency costs.²¹ This is not the first time Dialysis Care Centers has failed to include construction costs in an application for permit. For their Dialysis Care Center Beverly facility, Dialysis Care Centers had no construction or modernization costs and only a \$60,000 contingency.²² At the February 27, 2018 meeting, HFSRB staff expressed concerns that Dialysis Care Centers were not capturing all of the capital costs in their applications.²³ In response, Dialysis Care Centers said,

we have direct construction costs. And one of the things we did today was to have the builder, the landlord talk in the public comment this morning. He came in and said he's going to do a turnkey project for us. These are ways in which

¹⁸ Id. at 128, 171, 172

¹⁹ 70 Ill. Admin. Code §1120.130(a)(1).

²⁰ See Dialysis Care Center Rockford Application for Permit p 173.

²¹ Id. at 7

²² See Dialysis Care Center Beverly Application for Permit p 7.

²³ Transcript of February 27, 2018 Health Facilities and Services Review Board Meeting at 200.

we're very, very nimble and very, very creative in how to get our cost much lower.²⁴

Upon review of the letter of intent and proposed lease for the project, Dialysis Care Centers were not truthful in accounting for the costs to construct DCC Rockford. In the letter of intent, the Tenant Improvement provision specifically states, "Landlord will reasonably cooperate with Tenant to assist in timely completion of the Tenant Improvements at the Tenant's sole cost and expense."²⁵ Further, Section 5.2 of the proposed lease states, "All work necessary for the purpose of constructing Tenant's leasehold improvements shall be performed by the Tenant at the Tenant's sole cost and expense ("Tenant's Work")."²⁶ Based upon both the letter of intent for the lease and the proposed lease, Dialysis Care Centers are responsible for the cost of the tenant improvements; however, they only budgeted \$60,000 for build out of the facility space. Not only has Dialysis Care Centers not included all of the project costs, but they have not accounted for how they will fund the build out of the dialysis clinic. Dialysis Care Centers anticipates the cost to build, equip and furnish the clinic will only cost \$556,000.²⁷ As a point of reference, DaVita's projected cost to build out similarly situated dialysis facilities is approximately \$1 million. The HFSRB staff's concern regarding properly accounting for all capital costs is merited, and this project a negative finding on this criterion should be made unless should not be allowed to move forward until the HFSRB's staff's questions and concerns are adequately addressed by Dialysis Care Centers.

3. False Narrative: Respite Care

Dialysis Care Centers has presented five projects before the HFSRB. In its presentations, its representatives position its projects as "respite" facilities needed for patients who nearly exclusively use a home modality but need in-center care for limited reasons, noting "[a]t our core we're a PD company; we're a home dialysis company."²⁸ They claim a specialty dedicated facility is needed when their home peritoneal patients require in-center hemodialysis for a period of time whether due to infection or a home hemodialysis care giver needs a break. Further, they assert when temporarily placed at in-center dialysis facility their patients are told they cannot return to a home modality.²⁹ This is patently false. DaVita embraces home modalities as optimal therapies both in terms of quality of care and life and cost. It is committed to home modalities and increasing the number of patients on peritoneal dialysis ("PD") and home hemodialysis. In 2017, DaVita served over 23,000 home hemodialysis and PD patients, more than any other provider in the United States. DaVita would like to see more patients on home

²⁴ *Id.* at 201.

²⁵ *See* Dialysis Care Center Beverly Application for Permit p 32 (emphasis added).

²⁶ *Id.* at 42

²⁷ *See* Dialysis Care Center Rockford Application for Permit p 7.

²⁸ Transcript of April 17, 2018 Health Facilities and Services Review Board Meeting at 122.

²⁹ *See* Transcript of June 20, 2017 Health Facilities and Services Review Board Meeting at 284-285; Transcript of April 17, 2018 Health Facilities and Services Review Board Meeting at 126-127.

modalities due to better quality of life and improved clinical outcomes compared to in-center hemodialysis; however, as Dialysis Care Centers recognizes, “*home dialysis patients cannot be on home dialysis forever.*”³⁰ With respect to Rockford market, Dr. Mahmood, the nephrologist supporting the DCC Rockford application, has privileges at every in-center dialysis clinic in Rockford. Importantly, the patient’s attending nephrologist (i.e., Dr. Mahmood), not the clinic, determines the treatment plan for the patient and whether the patient can return to a home modality following a care problem at home. In turn, the clinical team carries out the treatment plan designed by the attending nephrologist who also oversees the dialysis treatments. If an in-center clinician tells a patient he or she cannot return to a home modality, it is based on the decision of the attending nephrologist. That physician’s decision would be due to a home dialysis fail - ineffectiveness or safety issues relating to the home modality.

If Dialysis Care Centers truly requires a respite dialysis facility for its patients, why do they want such a large facility? Despite the benefits and as the HFSRB members recognize, very few patients elect home modalities for dialysis treatment. Further, the number of home patients requiring respite care at any one time is a small sub-set of the home dialysis patient population and does not warrant a separately dedicated dialysis facility.

4. Dialysis Care Centers Has No Meaningful Record of Investing in Quality; DaVita Continuously Invests in Quality and Innovation;

a. *Dialysis Care Centers.* Dialysis Care Centers is rapidly expanding in Illinois representing that it offers a unique method and high quality services. In fact, throughout its application, Dialysis Care Centers states that quality care is its first priority. Neither the application for DCC Rockford or the information on its website, however, discusses quality or innovative care models for in-center dialysis. The company’s public information is limited to the descriptions of types of machines used for the various dialysis modalities, function of the kidneys and why they fail, what is chronic kidney disease, signs of ESRD, and when dialysis is needed. DCC Rockford also suggests that it has a special mode of care called Staff Enhanced home hemodialysis. First, as indicated by its name the model is for home dialysis which Dialysis Care Centers already offers in Rockford. Further, staff assistance in the home is not covered by government payors and 90% of patients listed for HSA 1 in 2016 are covered by government sponsored insurance products.

b. *DaVita.* In contrast, DaVita is at the forefront of quality and innovation in patient care and for the fourth year, DaVita led the industry in quality. In 2018, DaVita had the highest percentage of facilities meeting or exceeding CMS’s standards in the government’s two key performance programs the Five-Star Quality Rating System and the Quality Incentive Program (“QIP”), compared to the rest of the industry. With 93 percent of its centers rated with three-, four- or five-stars this year compared to 86 percent for the rest of the industry, DaVita lead the industry in quality. The QIP is part of CMS’s ESRD program to encourage dialysis centers to

³⁰ Transcript of June 20, 2017 Health Facilities and Services Review Board Meeting at 277.

meet or exceed certain performance standards. DaVita centers continually outperform the industry in the top clinical performance tier.

Initiatives DaVita has pioneered or leads the industry include:

- Leader in home hemodialysis and peritoneal dialysis treatment for patients with over 23,000 patients in 2017;
- Led the shift to integrated kidney care through establishment of chronic special needs plans (CSNPs)³¹ and End Stage Renal Disease Seamless Care Organizations (ESCOs);
- First renal-specific pharmacy, DaVita Rx;
- Launched Paladina Health, a direct to employer primary care business.

In November 2016, DaVita announced its partnership with Rock Health, the first venture fund dedicated to digital health and a leader in fostering health care innovation. The partnership will help facilitate direct connections between the diverse, innovative companies in Rock Health's portfolio and DaVita, to allow for opportunities to better serve DaVita's nearly two million patients, 67,000 teammates and 15,000 affiliated physicians around the world.

DaVita has taken on many initiatives to improve the lives of patients suffering from CKD and ESRD. These programs include Kidney Smart, IMPACT, CathAway, and transplant assistance programs. Furthermore, DaVita is an industry leader in the rate of fistula use and has the lowest day-90 catheter rates among large dialysis providers. During 2000 - 2014, DaVita improved its fistula adoption rate by 103 percent. Its commitment to improving clinical outcomes directly translated into 7% reduction in hospitalizations among DaVita patients.

³¹ CSNPs are a type of Medicare Advantage Plan (like an HMO or PPO) whose membership is limited to people with specific diseases or characteristics. CSNPs tailor their benefits, provider choices, and drug formularies to best meet the specific needs of the groups they serve.

DaVita opposes Dialysis Care Center's proposed project to establish a 12 station dialysis facility in Rockford, Illinois. Since the denial of DaVita's smaller Alpine Dialysis application, nothing has changed. As discussed throughout this letter, DaVita's proposed clinic was better positioned, and its application was superior to the DCC Rockford application. For these reasons, the proposed DCC Rockford application should not be approved.

Sincerely,



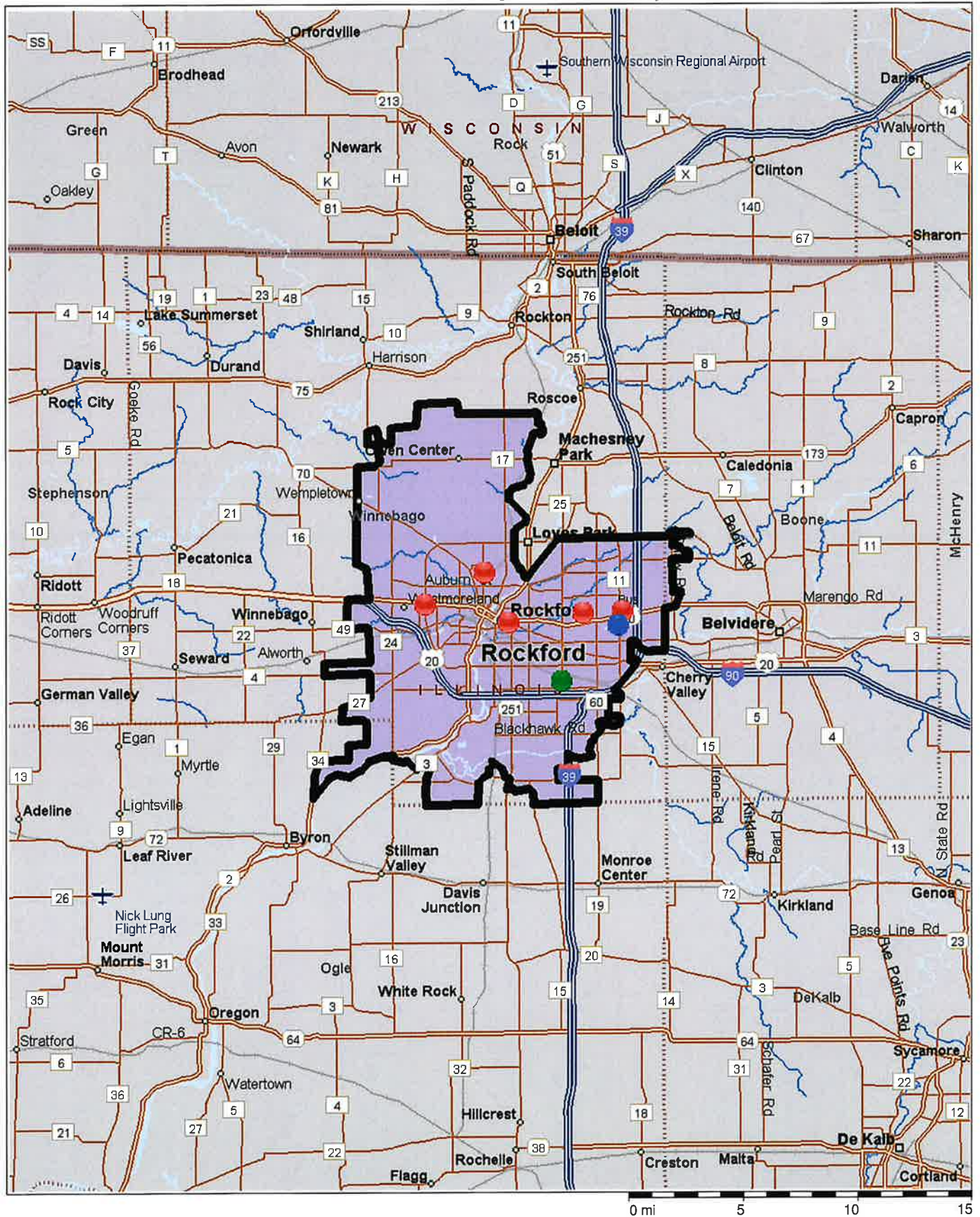
Mary Anderson
Division Vice President
DaVita, Inc.

June 27, 2018



Cathy A Pavolko

Rockford Existing Facilities Map



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